UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., Plaintiff, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	Case No. 16-cv-1251 (ER)

DECLARATION OF ERIC BURNESON

I, Eric Burneson, make the following declaration pursuant to 28 U.S.C. § 1746. This declaration is true and correct to the best of my knowledge, information, and belief, and is based on my personal knowledge and on information supplied to me by employees of the United States Environmental Protection Agency ("EPA" or the "Agency") under my supervision.

INTRODUCTION

1. I am Eric Burneson, the Director of the Standards and Risk Management Division in EPA's Office of Ground Water and Drinking Water. I have been employed by EPA since 1999 and I have held my current position since March 2014. As Division Director, I oversee the development of actions required under the Safe Drinking Water Act ("SDWA") to identify, analyze, and regulate contaminants in drinking water provided by public water systems in the United States. I currently supervise a staff of 56 permanent full-time and part-time federal employees.

2. Among my responsibilities is the direction of actions to establish the Contaminant Candidate List ("CCL") every 5 years under SDWA § 1412(b)(1)(B)(i), make the determination every 5 years whether to regulate at least 5 contaminants on the CCL under SDWA § 1412(b)(1)(B)(ii), and, where EPA determines to regulate a contaminant under SDWA § 1412(b)(1)(B)(ii), develop the national primary drinking water regulation ("NPDWR") for that contaminant as well as any necessary supporting analyses, coordinating with other EPA offices as necessary. When promulgating an NPDWR for a contaminant regulated under SDWA, EPA issues both (a) a maximum contaminant level goal ("MCLG") which is established at a level at which no known or anticipated adverse effects on the health of persons occur from exposure to the contaminant and which allows an adequate margin of safety, SDWA §1412(b)(4)(A), and (b) the maximum contaminant level ("MCL") which is the regulatory level for the contaminant and generally set as close to the MCLG as is feasible. SDWA § 1412(b)(4)(B).

3. In addition to the Agency's work on perchlorate that is the subject of this litigation, significant current regulatory responsibilities in my Division include ongoing revisions to rules governing lead in drinking water, activities related to lead in plumbing used for public drinking water, and analysis and regulatory activities related to perfluorinated compounds.

4. I have read the Consent Decree of October 18, 2016 (hereinafter "Consent Decree"). I understand that, under the Consent Decree, the Agency is required to sign for publication in the Federal Register a proposed Safe Drinking Water Act § 1412 MCLG and NPDWR for perchlorate by October 31, 2018. I submit this declaration in support of EPA's motion to extend this deadline by six months to April 30, 2019 and to explain the bases for the requested six-month extension.

BACKGROUND

5. Perchlorate is a contaminant in drinking water that may inhibit the active uptake of iodide by the thyroid gland. Lack of iodide can interfere with the production of thyroid hormones, which in turn play an important role in the regulation of metabolic processes throughout the body and are critical to brain development in infants and fetuses. As a result, a health concern associated with perchlorate in drinking water is the risk it may pose to pregnant women, their developing fetuses, and infants that may ingest the water (e.g., in breast milk or when mixed with formula).

6. EPA included perchlorate on the first, second and third CCLs that were published in 1998, 2005 and 2009, respectively. On October 10, 2008, EPA published a preliminary regulatory determination for perchlorate requesting public comment on its determination not to regulate on the basis that perchlorate did not occur with a frequency and at levels of public health concern and regulation of perchlorate did not present a meaningful opportunity for health risk reduction for persons served by public water systems (two of the three criteria for regulating a contaminant under SDWA). 73 Fed. Reg. 60,262 (Oct. 10, 2008). In August 2009, EPA published a supplemental request for comment on additional analyses the Agency had conducted to ensure that the Agency had considered all potentially affected life stages (age groups) when determining whether there is a meaningful opportunity for human health risk reduction of perchlorate through a NPDWR. 74 Fed. Reg. 41,883 (Aug. 19, 2009). After consideration of public comment on these additional analyses, on February 11, 2011, EPA made a determination to regulate perchlorate in drinking water and initiated the development of a proposed NPDWR for perchlorate. 76 Fed. Reg. 7762 (Feb. 11, 2011).

7. SDWA § 1412(e) provides that prior to proposal of an NPDWR, the Administrator must consult with the EPA Science Advisory Board ("SAB"). In 2012, my staff requested advice from the SAB on how best to consider and interpret life stages information, physiologically-based pharmacokinetic analyses,[1] epidemiological and biomonitoring data post-dating the 2005 National Academy of Sciences' health effects assessment for perchlorate that had informed the Agency's 2011 regulatory determination, and the totality of perchlorate health information to derive an MCLG. 77 Fed. Reg. 31,847 (May 30, 2012). In its May 29, 2013 response, the SAB recommended that EPA develop and use models to evaluate the health risk posed by perchlorate on sensitive populations rather than the reference dose from the 2005 National Academy of Sciences upon which the Agency's regulatory determination was based. As noted in its report, the SAB found "this data-driven [modelling] approach represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages than is possible with the default approach for deriving an MCLG."

8. Consistent with the direction of the SAB, EPA developed a two-step approach to deriving an MCLG for perchlorate. First, EPA scientists, along with scientists from the U.S. Food and Drug Administration ("FDA"), worked collaboratively to develop a biological model – the Biologically Based Dose Response ("BBDR") model – to predict the effects of perchlorate exposure on thyroid hormone levels in pregnant women, and second, EPA produced the "Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water" (the "Draft MCLG Approaches Report"), a draft approach for linking changes in a pregnant mother's thyroid hormones to adverse health effects in her child.

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[1] Physiologically based pharmacokinetic (PBPK) modeling is a mathematical modeling technique for predicting the absorption, distribution, metabolism and excretion of chemical substances in humans and other animal species.

The Draft MCLG Approaches Report allows the Agency to use the outputs (the changes in thyroid hormone levels in the mother) of the BBDR model in conjunction with scientific literature describing the health consequences of low thyroid hormone levels, to predict adverse health impacts on the offspring due to the mother's ingestion of specific levels of perchlorate in drinking water. EPA frequently develops and uses BBDR modeling to conduct health risk assessments. However, linking the predicted output from BBDR to neurodevelopmental outcomes through data found in scientific literature is novel.

PEER REVIEW

9. SDWA § 1412(b)(3)(A) requires the Agency to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices." Consistent with this requirement, and because the Agency's draft approach to deriving an MCLG contained two distinct steps, my office undertook a rigorous two-step independent expert peer review process of the BBDR model and the Draft MCLG Approaches Report. See https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0012.

10. After completing the steps necessary to identify expert peer reviewers and obtain public comment on nominated peer reviewers and their charge,[2] the Agency convened a meeting

[2] Consistent with EPA's March 21, 2013 policy, "Conflicts of Interest Review Process for Contractor-Managed Peer Reviews of EPA Highly Influential Scientific Assessment (HISA) and Influential Scientific Information (ISI) Documents," an EPA contactor selected a tentative list of panelists from candidates nominated by the public or identified by the contractor. The contractor selected the final members after considering public comment on the tentative list and consulting with EPA's Scientific Integrity Official. In addition, EPA solicited public comment on the scientific products subject to the two reviews and provided those comments to the peer reviewers for their consideration. For more information, see, e.g., 81 Fed. Reg. 87,553 (December 5, 2016) (announcing, among other things, the final list of BBDR model peer reviewers and charge questions and providing background on the peer review process); 82 Fed. Reg. 56,235 (November 28, 2017) (same for the Draft MCLG Approaches Report).

of the first expert peer review in January 2017. The final Peer Review Summary Report was submitted to EPA on March 29, 2017.

11. At the time the consent decree was signed, EPA anticipated that when the Agency received the peer review report in March, EPA would need one month to address its recommendations. This estimate was based on the Agency's expectation that the peer reviewers of the draft BBDR model would have relatively limited recommendations for revisions of the model, as EPA has considerable experience developing this type of model and the draft BBDR model for perchlorate integrated models that had been previously peer reviewed, including (a) the EPA Physiologically-Based Pharmacokinetic model (2009) for perchlorate. (b) the model developed by Lumen et al. (2013) for pregnant mothers and fetuses, (c) the iodide models developed by Fisher et al. (2013) for lactating rats. and (d) the model for lactating mothers and nursing infants by Fisher et al. (2016). However, the final peer review report received in March 2017 contained recommendations for much more extensive revisions to the model than expected, ultimately requiring six months to address rather than the one month originally anticipated, thus resulting in a delay of five months.

12. EPA determined after careful review of the report that it was critical to the accuracy and usefulness of the analysis to revise the draft BBDR model to improve thyroid hormone level predictions and to reduce uncertainty of modeling results. Not wanting to unnecessarily slow the process, EPA considered all of the peer reviewers' recommendations but focused most heavily on those that were anticipated to be most important for increasing the scientific rigor of the model and modeling results.

13. Model revisions focused on the following key peer reviewer recommendations: changing the life stage of concern modeled to predict thyroid hormone changes during early

(rather than late) pregnancy; incorporating the bodies' compensatory response to decreases in thyroid hormone levels by secreting thyroid stimulating hormones to prompt greater thyroid hormone production; enabling the model to address pregnant women with lower levels of iodide in their diet; calibrating the model and evaluating its behavior for upper and lower percentiles of the distribution of thyroid hormone levels in the population; and conducting an uncertainty analysis for key parameters. EPA scientists required five months longer to revise the BBDR model than the Agency had anticipated in October 2016 when the Consent Decree was entered. In my opinion, and in the opinion of my staff and other Agency management, it was critical for the Agency to complete these revisions prior to conducting the second stage of the analysis. The revisions greatly improved the accuracy of the model outputs and consequently will improve the quality of the overall analysis to predict adverse neurodevelopmental outcomes from ingestion of perchlorate.

14. In September, EPA published the first Federal Register notice pertaining to the second peer review (82 Fed. Reg. 43,354 (Sep. 15, 2017)), and convened the second independent expert peer review panel in January 2018. *See* 82 Fed. Reg. 56,235 (Nov. 28, 2017). Because the subject of the second stage of the peer review is an analysis that discusses revisions to the BBDR model and applies the revised BBDR model to predict health impacts due to perchlorate exposure, the extended work on the BBDR model necessarily delayed the second peer review. EPA presented the revised BBDR model to the panel and presented the Draft MCLG Approaches Report linking changes in a pregnant mother's thyroid hormones to adverse health effects in her child. In drafting that report, EPA scientists evaluated published epidemiologic studies and identified quantitative relationships between thyroid hormone levels in pregnant women and neurodevelopmental outcomes in their children. Using the BBDR model and these quantitative

relationships from the epidemiologic studies, EPA scientists presented approaches for characterizing the magnitude of impact perchlorate has on thyroid hormone levels in the pregnant mother and neurodevelopmental outcomes in her children.

15. The second expert peer review panel provided a final report with recommendations on March 29, 2018. The Agency had believed that any recommendations would be minor, as EPA had closely followed the SAB's expert advice for determining neurodevelopmental outcome and many of the peer reviewers were also members of the SAB panel. However, the recommended revisions were more extensive and required more time than the Agency had anticipated in October 2016, as discussed in the paragraph below.

16. After careful evaluation of the second expert peer review panel recommendations, EPA scientists worked as expeditiously as possible to make the following modifications to the Draft MCLG Approaches Report: updated the literature search to include scientific studies published since the last draft; reevaluated epidemiologic studies that had been previously excluded from the report; conducted a more systematic evaluation of the quality of epidemiologic studies; and reanalyzed the relationship between dose-response information relating maternal thyroid hormone levels to IQ from the data provided by one of the primary study authors. These revisions required an additional month of work beyond the five months already spent on revising the BBDR model, and beyond the one month that had been anticipated when the consent decree was entered. Incorporating both rounds of revisions resulted in six months of unanticipated additional technical work by EPA scientists.

REMAINING WORK

17. Under the Consent Decree approved by the Court on October 18, 2016, EPA agreed to a schedule under which the agency would complete its ongoing peer review process for

perchlorate and then develop a proposed MCLG and NPDWR. Completion of the expert peer review process was important to ensure a robust, peer reviewed health risk assessment which is the starting point for deriving the proposed MCLG and NPDWR for perchlorate. At the time that the Decree was entered, EPA expected to complete the external peer review process no later than October 18, 2017. That schedule allowed a year following the peer review to complete the actions necessary to develop the regulatory proposal in compliance with SDWA analytical and consultative requirements. As discussed above, the Agency is now six months behind schedule because of the unexpected delays in completing the peer review process.

18. EPA has a number of essential tasks to complete before the Agency can issue the proposed MCLG and NPDWR for perchlorate, which the Agency had hoped to do in the previous six months prior to the unanticipated delay. This significant technical and policy work is necessary to meet EPA's statutory obligations under SDWA and to ensure that our administrative record is robust and allows for meaningful public comment, thus enabling the agency to take final action on the proposal in a timely and defensible manner.

19. First, as noted above, when developing the MCLG and NPDWR for perchlorate (including the MCL), the EPA must first determine the health-based level (MCLG) because SDWA requires the MCL generally to be set as close as feasible to the MCLG. Deriving an MCLG was not possible until the completion of the peer review recommended revisions to the scientific quantitative tools—the BBDR model and the Draft MCLG Approaches Report—which inform the health risk assessment for perchlorate. We expect to complete the additional analyses necessary to complete the health risk assessment by November 2018.

20. Second, a critical aspect of the rulemaking process required by SDWA is the development of the Health Risk Reduction and Cost Analysis ("HRRCA"). The HRRCA is

required by Section 1412(b)(3)(C) for any proposed NPDWR that includes an MCL; EPA will be proposing one or more MCLs for perchlorate. Under the HRRCA provisions, EPA must prepare economic analyses that include the following for the proposed and alternative MCLs: quantifiable and nonquantifiable benefits (including from the reduction of co-occurring contaminants), quantifiable and nonquantifiable costs, incremental costs and benefits, the effects of the contaminant on the general population and on groups within the population identified as likely to be at greater risk of adverse health effects, any increased health risk that may occur as a result of compliance and other relevant factors, including the quality and extent of information, any uncertainties in the above analyses, and factors with respect to the degree and nature of the risk. While my staff has made considerable progress on the technical work that could be done during the period in which the Agency was conducting the expert peer review,[3] I expect that they will need until January 2019 to complete work on the HRRCA-related documents.[4] My office could not fully complete this step earlier because we needed to finalize the MCLG (which is derived after the conclusion of the peer review process) before completing the HRRCA requirements.

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[3] For example, my staff has completed the following HRRCA-related tasks that could be conducted prior to derivation of a proposed MCLG: an evaluation of the effectiveness of treatment technologies and identified Best Available Technologies ("BATs") for removing perchlorate, identification and evaluation of analytical methods to measure perchlorate in drinking water and updating occurrence estimates to reflect current conditions to inform the exposure assessment.

[4] HRRCAs are typically very lengthy technical documents, averaging around 200 pages in length. Examples of prior HRRCAs conducted by my staff include: (1) Health Risk Reduction and Cost Analysis Revised National Primary Drinking Water Standards for Radionuclides. December 2000. (https://www.epa.gov/sites/production/files/2015-09/documents/2009_04_16_radionuclides_regulation_radionuclides_rulemaking_prelimaryhrcca.pdf); (2) Economic Analysis for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule. December 2005. (https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1005OOX.txt); and (3) Arsenic in Drinking Water Rule Economic Analysis. December 2000 (https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20001YQT.TXT).

21. Additionally, because the NPDWRs are implemented by states, tribes and local governments, once EPA has developed potential options (informed by the MCLG) for a proposed rule, EPA conducts important consultations with State, local and tribal officials prior to proposal to gain a sense of any implementation issues that should be addressed in the rule. I expect that these consultations will begin in fall 2018 and should be completed within about four months.

22. In addition to the consultations described above, during August and early September, my staff and I will be presenting options for the perchlorate MCLG to the senior management of EPA for selection. After a decision by the Acting Administrator, my staff will complete drafting of the necessary preamble and rule documents for review by various offices in the agency, including the Office of Research and Development, the lead science office at EPA; the Office of General Counsel; the Office of the Administrator; and the Office of Land and Environmental Management ("OLEM"). OLEM is the EPA office that is charged with implementing the Resource Conservation and Recovery Act and Superfund programs; drinking water standards are considered in developing site-specific cleanup levels in these programs. I expect that EPA will conclude the rule drafting and internal reviews by early January and then to submit the rulemaking for review to the Office of Management and Budget ("OMB") for inter-agency review under Executive Order 12866 during which the Agency receives useful input from scientists in other federal agencies with considerable expertise in addressing perchlorate contamination.[5] During OMB review, in addition to interacting with and responding to requests

[5] For example, the Agency expects significant and valuable input during inter-agency review from the Food and Drug Administration, which addresses risks posed by perchlorate in food, and the Department of Defense and National Air and Space Administration, which are involved in remediation of certain sites contaminated by rocket fuel.

from the reviewing agencies, my staff will upload supporting documentation and studies to construct the rulemaking docket and will develop a communication plan. EPA anticipates that inter-agency review and any subsequent revisions to the proposal and analysis will be completed by late April.

CONCLUSION

23. The unanticipated delay in completing the external peer reviews has resulted in a corresponding delay in our completion of this proposed rulemaking. For the reasons described above, I expect the remaining technical work, drafting, and internal and external reviews can be completed by April 30, 2019. As demonstrated above, a six-month extension of the consent decree deadline to propose an MCLG and NPDWR for perchlorate is necessary to perform critical and required analyses to support the proposal and document the scientific findings and rationale, ensure that the analysis and impacts of the proposal are fully considered, and to provide for a robust and transparent record and rationale for public comment on the proposal.

24. If EPA is not granted an extension, the Agency is concerned that the quality of its analyses, especially related to the cost and benefit analysis as specified in the SDWA for the HRRCA, will suffer. The consultations and analyses described in this declaration help ensure that EPA's proposed rule not only meets the requirements of SDWA, but that it is in a shape that best facilitates public comment and timely completion of the final rule. As demonstrated above, addressing perchlorate in the nation's drinking water is a complicated endeavor. It is also one of significant public interest; EPA received approximately 39,000 comments on the notices leading to the 2011 final regulatory determination for perchlorate. If EPA's analyses and regulatory options are not fully formed, clearly drafted and tested through the internal and inter-agency consultation processes, the public's ability to make informed comments on the proposal will

likely be compromised. Poorly drafted proposals and supporting documentation can result in uninformed or confused comments, EPA publication of clarifications, additional analyses and/or options, and requests for supplemental comment, all of which may significantly delay final action on the proposal and ultimately complicate the record for judicial review. It is thus vital that all necessary care be taken at the proposal stage. An extension until April 30, 2019 is the minimum that would enable my staff to exercise that care.

I declare under penalty of perjury that the foregoing is true and correct, based on my personal knowledge and on information provided to me by EPA employees under my supervision.

Executed on: August 30, 2018
Washington, District of Columbia

By: _____

Eric Burneson
Director, Standards and Risk Management Division
U.S. Environmental Protection Agency